
MOOV CARE™, 1st WEB-APPLICATION DEDICATED TO REMOTE INDIVIDUALIZED FOLLOW-UP HAVING DEMONSTRATED SIGNIFICANT BENEFIT ON OVERALL SURVIVAL IN PATIENTS WITH ADVANCED LUNG CANCER

Jerusalem, Monday, June 6, 2016 – At the 2016 annual conference of the *American Society of Clinical Oncology*, Dr. Fabrice Denis, oncologist at Jean Bernard Cancer Center (Le Mans, France) presented during an oral session **the results of a randomized multicentric phase III study comparing the remote follow-up with MoovCare™ web-application to conventional follow-up by systematic scans** every 3 to 6 months, in patients followed-up for lung cancer with high risk of relapse after initial treatment phase (*A phase III trial exploring whether using a mobile device-friendly web application for symptom monitoring improves survival of patients with lung cancer – Late Breaking Abstract LBA9006*).

MoovCare™ is the **1st web-application**¹ based on clinical symptoms telemonitoring enabling the active and individualized remote follow-up of **patients with lung cancer** after treatment. It **enables early detection of relapse or complications requiring adjustment of patients care**.

A significant Overall Survival gain of 7 months

At the planned interim analysis of the phase III study results, the **median overall survival was 19 months** (CI 95%: 12.5 - not reached) **in the experimental arm MoovCare™ and 12 months** (CI 95%: 8.6 to 16.4) **in the standard arm** ($p = 0.0014$). This highly significant difference in favor of the experimental arm led the study independent data monitoring committee (IDMC) to stop the randomization. The **overall survival rates after 1 year** were 74.9% (CI 95%: 59.4 - 84.1) in the experimental MoovCare™ arm and 48.5% (CI 95%: 31.9 - 63.2) in the standard arm, i.e. **a difference of 26% in favor of the experimental arm. The number of deaths after 1 year was three times lower in the MoovCare™ arm** (HR = 0.325; CI 95% 0.16 - 0.67, $p = 0.0025$).

The sub-groups analysis shows a statistically significant overall survival improvement in non-small cell lung cancer and small cell lung cancer, stage IIIB/IV, subgroups. For the sub-group of patients receiving maintenance treatment for which every 3 weeks monitoring was standard, a statistical difference was not reached.

A better overall condition when diagnosing relapse that enables optimal patients care

Performance Status (PS) at the time of the relapse was 0 or 1 (corresponding to a good overall condition) in 77% of patients in the experimental MoovCare™ arm *versus* 33% of patients in the standard arm ($p < 0.001$), thus enabling the implementation of an "**optimal**" **treatment of the relapse in respectively 74% of MoovCare™ arm patients compared to only 33% of patients in the control arm** ($p < 0.001$).

At an advanced stage, the most effective lung cancer treatments require a good overall condition of the patients because of their potential toxicities. **The detection of relapse and complications from the first clinical signs optimizes patients care, when the patient's overall condition is still preserved.**

¹ A web-application is a digital application accessible from any internet browser, requiring no download via any download platform from various mobile operating systems (stores)

A significant impact on quality of life

Quality of life was significantly better in the MoovCare™ experimental group, whatever the reference scale used: FACT-L (p = 0.02), FACT-G (p = 0.01) and FACT-L TOI (p = 0.04)². The MoovCare™ follow-up enabled to reduce the frequency of calls from patients and the **compliance** to the remote follow-up (number of actual inputs compared to the number of theoretical maximum inputs) was **very high (84%)**.

Medico-economic benefits

When comparing the cost of monitoring in both arms (number of imaging, number of consultations and cost of medical transport), **MoovCare™ halve the number of physical examinations and reduce by 36% imaging examination costs**. It did not generate specific costs and the average weekly time spent by the medical team was only 15 minutes to manage an active line of 60 patients followed-up with MoovCare™.

« *MoovCare™ improves the relevance of physical examinations and consultations* », says Dr. Fabrice Denis.

The 1st phase III study that has evaluated the impact of a follow-up web-application on the prognosis of cancer patients.

For the first time in the world, a prospective, multicentric, randomized phase III study has been performed to correlate the effectiveness of an individualized follow-up with MoovCare™ with survival, quality of life and optimization of advanced lung cancer patients' care.

MoovCare™, helping the early detection of relapse and complications, enables to improve cancer care and to reduce both mortality and the number of unnecessary imaging examinations.

« *This is a patient follow-up individualization tool for carrying out the right exam at the right time* », says Dr. Fabrice Denis.

MoovCare™: when clinical and technological experts meet

With 1.8 million new cases diagnosed each year and 1.59 million deaths³, lung cancer remains one of the most common and deadly cancers in the world. It is often diagnosed at an advanced stage of the disease and, for one in two patients, straightaway in metastatic phase⁴. The current patient follow-up methods, after initial treatment, nowadays are misjudged and relapse is often diagnosed too late for the patient to benefit from an optimal treatment because of his deteriorated overall condition.

Invented by Dr. Fabrice Denis and developed by SIVAN Innovation, **MoovCare™** is a web-application based on an algorithm analyzing the dynamics of patient's clinical symptoms. It enables the patient (or a patient's relative) to fill in from home, **every week** -ideally at fixed day and time- **or upon the occurrence of a new event**, a **table of 12 clinical symptoms** but also to leave free text messages to the care team. In case of identification of anomalies, an alert is sent to the medical team who contacts the patient quickly to confirm if it is necessary to perform additional examinations or start a new treatment.

² FACT-G: Functional Assessment of Cancer Therapy – General

FACT-L: Functional Assessment of Cancer Therapy – For patients with Lung cancer

FACT-TOI: Functional Assessment of Cancer Therapy – Trial Outcome Index (for Lung Cancer)

³ http://globocan.iarc.fr/Pages/fact_sheets_cancer.aspx (seen 05/19/2016)

⁴ HAS. Guide du parcours de soins Tumeur maligne, affection maligne du tissu lymphatique ou hématopoïétique Cancers broncho-pulmonaires, Juillet 2013

The specificity and sensitivity of the algorithm had first been validated through 2 phase II studies demonstrating that MoovCare™ remote follow-up enabled the **detection of relapses 5-6 weeks before systematic scan in every 3 months scheduled follow-up visit.**

The collaboration between Dr. Fabrice Denis and the research & development company SIVAN Innovation, specialized in e-health field, enabled the further development of MoovCare™ through a **prospective, randomized, multicentric phase III study.** The objective of this study was to measure the survival benefit of a remote individualized follow-up of patients with MoovCare™.

A total of **133 patients**, recruited and followed-up in 5 oncological centers (public and private) **were randomized** between June 2014 and January 2016, and at the end **121 were analyzed (intent to treat population).** Patient characteristics were similar in both arms of the study: 96% stage IIIa/IIIb/IV (of which 40% stage IV) and 4% stage II. During the follow-up, approximately 60% of patients did not receive any treatment, 25% were receiving maintenance treatment and 15% treatment with Tyrosine Kinase Inhibitor.

The **Institut de Cancérologie de l'Ouest (UNICANCER – Nantes, France)** was the promotor of this clinical study and carried out methodological coordination, results analysis and compliance with good clinical practices for all the centers involved in the study.

On the basis of these clinical data, **MoovCare™ is currently in a CE mark procedure in Europe** and discussions are ongoing with the French health authorities regarding the possibility of its reimbursement.

SIVAN Innovation wants MoovCare™ to be accessible to the largest possible number of patients. This web-application will first be available to patients and healthcare professionals in France (2017), where it has been developed, in the main European countries, the USA and Israël, and then gradually in the rest of the world. MoovCare™ is also under development for about fifteen other indications in Oncology, especially including Lymphoma, in partnership with Takeda France.

« Through the **ambitious MoovCare™ clinical development program, we hope to become a major stakeholder in cancer follow-up through web-applications and a partner of the medical community**», says Daniel Israel, founding President of SIVAN Innovation.

In conclusion, the individualized remote follow-up with MoovCare™ enables:

For the patient

- An earlier diagnosis of relapse resulting into an overall survival gain of 7 months
- A diagnosis of relapse in better overall physical condition enabling more often to implement an optimal treatment (74% vs 33% for patients followed-up in a conventional way)
- A better quality of life compared to conventional follow-up
- A decrease of patient anxiety between two follow-up visits

For the medical staff

- To propose an individualized follow-up to patients
- To be able to intervene at the right time to diagnose the relapse
- To be able to prescribe optimal treatment of the relapse in optimal conditions
- To optimize the relevance of consultations and physical examinations without any inappropriate alerts

For the society

- An improvement of lung cancer care
- Optimization of monitoring costs

About MoovCare™

MoovCare™ is the 1st web-application dedicated to follow-up and early detection of relapse in advanced lung cancer patients.

Being both a science and technology challenge, MoovCare™ benefited from a full and rigorous clinical development which included two phase II studies and one phase III study, which primary evaluation endpoint was overall survival.

The MoovCare™ algorithm is based on the analysis of clinical symptoms (from the cancer semiology) inputted each week by the patient. MoovCare™ generates specific alerts directly sent to the medical team who may then intervene at the right time.

MoovCare™ was invented by Dr. Fabrice Denis and developed by SIVAN Innovation that finances its clinical development and carries out its industrial deployment, through the technological integration of the algorithm used in a web-application on various data media (computer, tablet or smartphone) enabling data securing and processing.

MoovCare™ is currently in a CE mark procedure in Europe. It is not available yet on the market.

About SIVAN Innovation

Research and Development company based in Israel, SIVAN Innovation is essentially dedicated to designing and validating innovative IT health applications.

Located in the heart of the Israeli “start-up nation” in Jerusalem, SIVAN Innovation benefits from **unique facilities for research, innovation and technological software integration** and eHealth digital solutions for:

- ➔ **supporting health professionals** in their medical daily practice,
- ➔ **improving patients care**, from prevention to follow-up.

Valuable incubator for innovation, SIVAN Innovation analyzes the medical environment and interacts with the health and IT stakeholders. It has a medical center that enables it to combine the precision of computer technologies, the scientific requirement and the clinical expertise.

At a time when connected items and eHealth set in the medical landscape, **SIVAN Innovation wishes to develop its technological expertise focused on patient’s needs**. Enabling the patient to become an active participant of his own health, **optimizing the patient-doctor communication**, improving the quality and pertinence of information provided to the physician: these are SIVAN Innovation’s objectives.

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